IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

ROQUETTE FRÈRES,

Plaintiff,

Plaintiπ,

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C. A. No. 06-540-GMS

SPI PHARMA, INC., et. al.

Defendants.

MEMORANDUM OPINION

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Wilmington, Delaware June 25, 2009

THYNGE, U.S. MAGISTRATE JUDGE

PROCEDURAL BACKGROUND

Plaintiff, Roquette Frères ("Roquette"), a French company, filed this patent infringement action against SPI Pharma, Inc. "(SPI"), a Delaware corporation, on August 31, 2006, alleging that SPI's MANNOGEM™ EZ¹ spray dried mannitol product infringes United States Patent No. 5,573,777 (the "'777 patent"). On October 20, 2006, Roquette filed its first amended complaint adding Drytec Ltd., a British corporation, as an infringing defendant.² On December 6, 2006, Drytec Ltd. moved to dismiss for lack of personal jurisdiction. Limited discovery on jurisdiction occurred and briefing followed. On May 21, 2007, Roquette moved for leave to file a second amended complaint to add three entities as co-defendants, specifically Drytec Contract Processing Ltd. ("Drytec CP"), Anhydro U.K. and Anhydro Holding A/S ("Anhydro Holding"). Drytec CP is also a British corporation, while Anhydro Holding is a Danish company.³

On June 13, 2007, during a telephonic conference, the court addressed Roquette's request for additional jurisdictional discovery in connection with its motion

¹ Although the complaint and subsequent amendments thereto reference MANNOGEM™ EZ as the infringing product, from the discussions with counsel during discovery disputes and the supplemental briefing, it is apparent that other spray dried mannitol products, such as Mannitol HS, are also accused. Therefore, reference to MANNOGEM™ EZ or mannitol product shall include all alleged infringing products.

² According to defendants, Drytec Ltd. changed its name to Anhydro U.K., Ltd. ("Anhydro U.K.") on January 1, 2007. As a result, defendants maintain that Anhydro U.K. "has taken the place of Drytec Ltd. as a party and is not properly an *additional* defendant. Roquette "accepts that representation so long as it is understood that both entities are subject to discovery as party defendants and that any relief accorded by this Court applies to both entities. . . ." Throughout the opinion, unless otherwise noted, when the court refers to Anhydro U.K., it is also referring to the predecessor, Drytec Ltd.

³ Drytec CP, Anhydro U.K. and Anhydro Holding collectively are referred to as Co-Defendants.

for leave to amend. As a result of that teleconference, it was clear that should the court grant Roquette's motion to amend, another motion to dismiss for lack of *in personam* jurisdiction would be filed, with another round of briefing on the same issues as in the original briefing. The court granted Roquette's motion to amend, ordered it to plead with more specificity its allegations of patent infringement, in particular the averments directed to contributory and inducement of infringement, and granted its request for additional jurisdictional discovery. Rather than dealing with potential serial briefing, the parties were to submit a proposed scheduling order for submission of briefs on a consolidated motion to dismiss for lack of personal jurisdiction by Co-Defendants.⁴ This is the court's decision on Co-Defendants' motion.⁵

PARTIES' POSITIONS

Co-Defendants' Arguments:

Co-Defendants maintain that all are foreign corporations with no ties to the state

⁴ Since briefing was completed, Roquette filed a motion for leave to file a supplemental answering brief in opposition based on the recent deposition of Rana Kayal, President of SPI, to which *all* defendants, including SPI, filed an opposition. The bases of their opposition is that that filing is not new evidence; is not dispositive of any jurisdictional issue presently pending; is an attempt to add factual material to the record in violation of the court's prior discovery rulings; and Roquette's attachment of its supplemental brief to its motion is in violation of the court's local rules. Roquette responded noting that SPI was not a party to the motion to dismiss and argues that its response is improper. See D.I. 129, 132,133. Approximately ten days before the filing of defendants response, SPI filed a motion to dismiss, incorporating by reference Co-Defendants' briefing of their motion to dismiss. Thereafter, Roquette moved again for leave to file an additional supplemental brief, which defendants opposed. See D.I. 171, 180, 181.

⁵ The parties consented to the jurisdiction of the Magistrate Judge to decide the motion to dismiss for lack of personal jurisdiction.

of Delaware.⁶ They rely on the following facts which they assert are undisputed. Drytec CP, a private British company, operated as a toll manufacturer for SPI in the United Kingdom for its MANNOGEM™ EZ product between October 2003 and November 2005.⁷ According to Co-Defendants, SPI had raw materials shipped to the United Kingdom. Drytec CP had no involvement whatsoever in the requisition or shipment of such materials. The raw materials were stored in a bonded warehouse until a freightforwarding company, paid by SPI, transported those materials to Drytec CP. Any finished MANNOGEM™ EZ was stored in a facility near the toll manufacturing plant, which was eventually picked up by a freight-forwarder hired by SPI for shipment from the United Kingdom to SPI's plant in Grand Haven, Michigan. Co-Defendants claim

⁶ Co-Defendants list various activities which they do not do and traditionally would impart personal jurisdiction under the Delaware Long Arm statute 10 Del. C. § 3104(c). They represent that none have ever been authorized, registered or qualified to do business in Delaware nor have they ever maintained an office, place of business. factory or showroom in that forum. Further, they have never had a registered agent for service of process nor has any officer, employee, agent or representative of them had an office in the state. None of the Co-Defendants has an interest in, uses or possesses any real estate or personal property in Delaware. They assert that none of them provide insurance or acts as a surety in Delaware. Co-Defendants confirm that none of them has a mailing address, telephone listing or bank account nor regularly does or solicits business, engages in any other persistent course of conduct or services or derives substantial revenue from services or things used or consumed in the state. Co-Defendants never transacted any business or performed any character of work or service nor contracted to supply services or products in Delaware. They have never directed any advertising specifically towards residents of the state. In making these representations, Co-Defendants rely upon the declarations of Biarne Henning Jensen. who is Vice President of Technology of Anhydro Holding and Paul C. Kennet, who is Managing Director of Anhydro U.K. and Drytec CP.

⁷ Relying on *Eli Lilly & Co. v. Zenith Goldline Pharmas, Inc.*, 172 F. Supp. 2d 1060, 1068 n.9 (S.D. Ind. 2001), Co-Defendants define toll manufacturing as "a type of arrangement, where one party owns the input and the output of the manufacturing process undertaken by another party. . .". Under such a relationship, "one party produces products owned by another party." *Wassal PLC v. La Miranda Products Co., Inc.*, 1993 U.S. Dist. LEXIS 16609, at *4 (S.D.N.Y. Nov. 24. 1993).

that throughout the manufacturing process, Drytec CP never owned any of the materials; rather, SPI retained ownership and title to those materials, whether raw, intermediate or finished. They further assert that Drytec CP never shipped any MANNOGEM™ EZ from the storage facility to other locations in England or from the United Kingdom to the United States. They also contend that Drytec CP never made used, sold, offered to sell or imported MANNOGEM™ EZ within or to Delaware or anywhere in the United States. They represent that since November 2005, SPI has had no further business dealings with Drytec CP.⁸

Regarding Anhydro U.K., another private British company, Co-Defendants maintain that equipment was sourced from it by Drytec North America LLC. Drytec North America entered into an equipment-supply agreement with SPI in November 2003 related to SPI's spray-drying plant in Michigan. For the equipment it provided, Anhydro U.K. shipped directly to Michigan or to other locations for eventual shipment to Michigan. It never shipped any equipment to Delaware. Co-Defendants state that pursuant to the agreement, Drytec North America provided standard spray-drying equipment which could be used for purposes other than to spray-dry mannitol.

Anhydro U.K. denies that it has ever made, used, sold, offered to sell or imported MANNOGEM™ EZ within or to Delaware or anywhere in the United States.⁹

Anhydro Holding, a private Danish company, is the parent company of Anhydro

⁸ For the representations regarding Drytec CP's relationship with SPI, Co-Defendants rely upon the declaration of Paul Kennet.

⁹ In addition to the declaration of Paul Kennet, for the representations concerning Anhydro U.K., Co-Defendants rely on the declaration of Colleen Blackney, the Marketing Manager of SPI.

U.K. Holding, Ltd., a British company, which owns Anhydro U.K. and Drytec CP.

According to the Kennet declaration, Anhydro Holding operated solely in Denmark, and has never had any business relationships with SPI or any connection to Delaware. It never actively directed or controlled the day-to-day business operations of Anhydro U.K. or Drytec CP. It also denies that it ever made, used, sold, offered to sell or imported MANNOGEM™ EZ within or to Delaware or the United States.

Co-Defendants contend that since their activities do not meet the requirements for specific jurisdiction, there is no basis for the exercise of personal jurisdiction under 10 *Del. C.* § 3104(c)(1)-(3) and (5)-(6) because no act actually occurred in Delaware from which the cause of action asserted arose. Co-Defendants point out that although Drytec CP toll manufactured the accused mannitol product, all work or services were performed in the United Kingdom. They note that SPI was solely responsible for importation. They maintain that Roquette's reliance upon PIERS information is misplaced, since those documents confirm that SPI, rather than Drytec CP or Drytec Ltd., was the importer. In support of that argument, the Co-Defendants rely on U.S. Customs documents regarding the shipment of the alleged infringing product from the United Kingdom to the United States, which clearly show SPI as the importer.

Regarding Roquette's argument that Anhydro U.K. transacted business in Delaware because it supplied SPI equipment for a spray-drying plant, Co-Defendants counter that all evidence proves that such equipment was supplied to SPI in Michigan and not Delaware.

¹⁰ Applied Biosystems, Inc. v. Cruachem, Ltd., 722 F. Supp. 1458, 1466 (D. Del. 1991).

Co-Defendants rely on case law from this jurisdiction to support their proposition that personal jurisdiction over a foreign holding company in patent litigation cannot be maintained solely because of the holding company's corporate relationship with the alleged infringing subsidiary.¹¹ They argue that in light of the total absence of contacts or dealings with SPI or the state of Delaware, the mere fact that Anhydro Holding is a corporate parent is insufficient for the application of personal jurisdiction over it.

Because they do not regularly conduct or solicit business, derive substantial revenue from services or things used or consume or engage in any persistent course of conduct in Delaware, Co-Defendants posit that general personal jurisdiction under § 3104(c)(4) may not be imposed. They rely upon the lack of sufficient contacts previously discussed herein.

Co-Defendants argue because Roquette has failed to show any activities in the state of Delaware, there is no evidence that they "purposefully directed activities at residents of the forum nor that the litigation results from alleged injuries that arise out of or related to those activities" as required under *Deprenyl Animal Health, Inc. v. University of Toronto Innovations Foundation.* The limited activities of Anhydro U.K. and the absence of any activities in either the United States or Delaware by Drytec CP and Anhydro Holding, Co-Defendants conclude, do not allow the exercise of specific jurisdiction under the Due Process Clause.

Because Roquette must show more than minimum contacts and prove that they

¹¹ See id. at 1472; Monsanto Co. v. Syngenta Seeds, Inc., 443 F. Supp. 2d 636, 646-647 (D. Del. 2006); Telcordia Technologies, Inc. v. Alcatel S.A., C.A. No. 04-874 GMS, 2005 WL 1268061, *3-*8 (D. Del. May 27, 2005).

¹² 297 F.3d 1343, 1350 (Fed. Cir. 2002).

have "continuous and systematic business contacts" with the state, in the absence of such evidence, Co-Defendants submit that the due process requirements for general personal jurisdiction have not been met.

Finally, Co-Defendants urge that their lack of Delaware contacts fails to satisfy the due process requirements of the "traditional notions of fair play and substantial justice."¹³

Roquette's Arguments:

Roquette counters that Delaware's Long Arm statute authorizes the exercise of personal jurisdiction over Co-Defendants. It argues that Kennet's testimony in both his deposition and declaration is incorrect by pointing to SPI documents which show that Anhydro U.K. appointed and maintained an agent in Delaware to deliver MANNOGEM™ EZ to SPI in the United States for sale.¹⁴ It points to a draft letter sent by SPI to Anhydro U.K., designating SPI as Anhydro U.K.'s registered agent, which Anhydro U.K. later acknowledged in another document that "SPI have [sic] been appointed the USA representatives [sic] for this product as requested." Roquette also relies upon documents submitted by Co-Defendants, specifically the commercial agreement between Drytec CP and SPI which provided that for compliance with FDA regulations, Drytec CP "shall name SPI Pharma as official agent for this material."

Roquette relies on other documents to support the argument that the Co-

¹³ International Shoe Co. v. Washington, 326 U.S. 310, 316 (1945).

¹⁴ Because MANNOGEM™ EZ is a pharmaceutical product, Roquette notes that a foreign manufacturer of such products is required by the U.S. Food and Drug Administration to appoint and maintain a statutory agent in the United States in connection for the import and sale of it.

Defendants satisfy the requirements of § 3401(c)(2). It points to a series of documents which allegedly evidence continuing deliveries of the mannitol product to SPI at three locations in Delaware. Roquette contends that those documents reflect deliveries from Drytec CP and Anhydro U.K. Roquette maintains that those business transactions occurred, in part, as a result of the toll manufacturing agreement, which allegedly resulted from negotiations that occurred in Delaware. Roquette emphasizes the language of that agreement which required Drytec CP to provide composite samples of the product for final quality assurance testing by SPI. 15 It relies on an internal SPI document dated February 22, 2001, which Roquette claims shows a direct shipment by Co-Defendants to SPI of three tons of accused product. It also notes the email of October 17, 2002, wherein Anhydro U.K. advised SPI that product samples would be sent through UPS that day and a subsequent SPI report as confirming that the samples were sent to SPI in New Castle, Delaware. As a result, Roquette maintains that such contacts are sufficient to meet the requirements of § 3104(c)(1) under Phillips Electronic North American Corp. v. Contec Corp. 16 the contracts provision of § 3104(c)(2); and, § 3104(c)(3) (when a non-resident or its agent causes a tortious injury in the state by an act or omission in the forum) under Applied Biosystems, Inc. v. Crauchen Ltd. 17

Contrary to Co-Defendants arguments and the testimony of Kennet that there were no visits by their officers to Delaware, Roquette relies on SPI documents which

¹⁵ Roquette asserts that based on the quantity shipped there is "no evidence that the shipments were limited to" just quality assurance.

¹⁶ 2004 WL 503602 (D. Del. Mar. 11, 2004)

¹⁷ 772 F. Supp. 1458, 1467 (D. Del. 1991).

indicate that the Managing Director of Drytec CP and Anhydro U.K., J.M. Pope, met with SPI executives regarding plans for the manufacture of spray-dried mannitol.¹8 Roquette argues that those documents show that Co-Defendants regularly solicited business or engaged in a persistent course of conduct in Delaware sufficient to meet the requirements of § 3104(c)(4). Moreover, it submits that from the documents, Co-Defendants derived substantial revenue from their long term business dealings with SPI, including the manufacture of MANNOGEM™ EZ and the sale of the spray-drying equipment.¹9

Regarding Anhydro Holding, Roquette posits that personal jurisdiction exists because of its "review and approval of the toll manufacturing agreement, in addition to its self-proclaimed status as head of the 'one single entity' encompassing all of the Drytec Entities. . . ."

As to the due process analysis, Roquette disputes that Co-Defendants' contacts were minimal or not continuous and systematic by pointing to their documented conduct, including their designation of Delaware-based SPI as their registered agent; sending a Managing Director and a Quality Control manager to SPI's Delaware offices;

¹⁸ In its first supplemental brief, Roquette also relies on the deposition of Rana Kayal, President of SPI, who testified that based upon his review of the October 2, 2000 letter, he believed that the three facilities that Pope visited were Grand Havens, Michigan, Septemes, France and Lewes, Delaware. In its second supplemental brief, Roquette points to a memo dated September 17, 2000 authorized by Kayal which confirms that Pope visited Delaware in 2000. It also noted that Peter Dickinson, the former Quality Control Manager for Drytec CP, confirmed that he visited SPI's facility in New Castle, Delaware on one occasion which occurred many years ago.

¹⁹ Roquette refutes as irrelevant Co-Defendant's argument that such equipment was delivered to Michigan since the contract was entered with Delaware-based SPI to which invoices for the components were billed to and paid by SPI in Delaware.

contracting with SPI in Delaware and arranging shipments of the accused product to Delaware-based SPI. In light of the documents cited, Roquette disagrees that Co-Defendants' activities occurred in the United Kingdom and submits that they contributorily infringed and/or induced infringement by selling in the United States components to SPI needed for manufacturing MANNOGEM™ EZ. Roquette claims that consideration and approval of the spray-drying plant, which was ultimately built in Michigan, the review and approval of its design, and the financing of and payments for the plant were done by SPI in Delaware, as evidenced by the invoices from Co-Defendants. Roquette maintains that Co-Defendants' purposeful conduct, targeted at SPI in Delaware, supports a finding for personal jurisdiction, which would not offend the notions of fair play and substantial justice.

DISCUSSION

Standard of Review

Under a motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(2), the court must "accept as true all allegations of jurisdictional fact made by the plaintiff and resolve all factual disputes in the plaintiff's favor."²⁰ Rule 12(b)(2) requires the court to dismiss a case when it lacks personal jurisdiction over the defendant.²¹ In order for personal jurisdiction over the defendant to exist, the plaintiff must allege facts that are sufficient to satisfy two requirements: statutory and constitutional. Under the statutory requirement, the court's analysis is whether there is a statutory basis for jurisdiction

²⁰ Monsanto Co. v. Syngenta Seeds, Inc., 443 F. Supp. 2d 636, 642 (D. Del. 2006).

²¹ E.I. DuPont de Nemours & Co. v. Rhodia Fiber & Resin Intermediates, 197 F.R.D. 112, 119 (D. Del. 2000).

under the forum's long-arm statute.²² The issue for review of the constitutional basis is whether the exercise of jurisdiction comports with the defendant's right to due process.²³ Therefore, in determining whether personal jurisdiction exists, the court must engage in that two step analysis.

When a jurisdictional defense is raised, the burden rests with the plaintiff to establish with reasonable particularity the required minimum contacts between the defendant and the forum state.²⁴ A plaintiff must establish either specific jurisdiction or general jurisdiction. Specific jurisdiction applies when the cause of action arises from contacts within the forum state; general jurisdiction occurs when a defendant has continuous and systematic contacts with the state, regardless of whether those activities are related to the particular cause of action.²⁵

Delaware Long Arm Statute

The Delaware Long Arm statute, 10 Del. C. § 3104 provides, in pertinent part:

- (c) As to a cause of action brought by any person arising from any of the acts enumerated in the section, a court may exercise personal jurisdiction over any nonresident, or a personal representative, who in person or through an agent:
- (1) Transacts any business or performs any character of work or service in the State:
- (2) Contracts to supply services or things in this State;
- (3) Causes tortious injury in the State by an act or omission in this State;
- (4) Causes tortious injury in the State or outside of the State by an act or omission outside the State if the person regularly does or solicits

²² Under Fed. R. Civ. P. 4(e), a federal court may assert personal jurisdiction over a nonresident of the state in which the court sits to the extent authorized by the law of that state.

²³ International Shoe Co. v. Washington, 326 U.S. 310 (1945).

²⁴ *Monsanto*, 443 F. Supp. 2d at 642.

²⁵ Helicopteros Nacionales de Columbia, S.A. v. Hall, 466 U.S. 408, 414, 416 (1984).

business, engages in any other persistent course of conduct in the State or derives substantial revenue from services, or things used or consumed in the State;

- (5) Has an interest in, uses or possesses real property in the State; or
- (6) Contracts to insure or act as surety for, or on, any person, property, risk, contract, obligation or agreement located, executed or to be performed within the State at the time the contract is made, unless the parties provide otherwise in writing.

Subsection (c)(1)-(3) and (5)-(6) are specific jurisdiction provisions, where there must be a nexus between the cause of action and the conduct of the defendant as a basis for jurisdiction.²⁶ Subsection (c)(4) is a general jurisdiction provision, which requires a greater extent of contacts, but applies when the claim is unrelated to forum contacts.²⁷ The Delaware Supreme Court applies a liberal construction to § 3104 to the maximum extent possible in order "to provide residents a means of redress against those not subject to personal service within the State."²⁸

Agency

Section 3104(c) confers jurisdiction over a nonresident "who through an agent" does the activities enumerated in subsections (1) through (6). The language of the statute provides that those activities must be done by the agent – acting under either the control, for the benefit of or on behalf of the nonresident, because "[a]n agency relationship alone . . . is not sufficient to confer jurisdiction." Roquette argues because SPI was designated as an "agent" under 21 C.F.R. § 207.40, that operates as conferring jurisdiction. SPI, however, must have operated as an "agent" doing the

²⁶ Monsanto, 443 F. Supp. 2d at 642.

²⁷ Applied Biosystems, Inc., 772 F. Supp at 1466.

Virgin Wireless, Inc. v. Virgin Enterprises Ltd., 201 F. Supp. 2d 294, 299 (D. Del 2002) (quoting Boone v. Oy Partek Ab, 724 A.2d 1150, 1156-57 (Del. Super. 1997).
 Applied Biosystems, Inc., 772 F. Supp at 1463.

activities enumerated in § 3104(c) for the Co-Defendants. The case law and the documents submitted do not support Roquette's position.

The documents upon which Roquette relies show that in 2003, during the negotiations of the toll agreement, SPI required Drytec CP and/or Anhydro U.K. to appoint it as the statutory agent to the FDA to enable SPI to import and sell MANNOGEM™ EZ in the United States. In an email dated April 23, 2003, from SPI to Drytec Ltd., SPI commented:

I have been requested to forward a copy of the letter to authorize SPI as your agent in the U.S. *This is required in order for SPI to import product and get it to clear customs.*³⁰

The letter of the same date, addressed to the FDA and attached to the email, provided that Drytec Ltd. was submitting a registration form, as required under a new regulation, which noted SPI as its agent. Further, in a subsequent email dated June 13, 2003, Drytec confirmed that the designation of SPI as its statutory agent was merely a formality and not an agency relationship for its benefit:

We agreed to assist SPI in supplying what information we had to *enable SPI* to use us in *their production* of the product [MANNOGEM™ EZ]. We have been sent forms for FDA registration by SPI and have been assured that this is a formality. SPI have [sic] been appointed the USA representatives [sic] for this product *as requested*.³¹

Further, contrary to Roquette's arguments, the tolling agreement, dated October 1, 2003, supports the Kennet declaration on the issue of agency. The agreement provides that Drytec CP "shall toll manufacture spray dried mannitol/sorbitol products (MANNOGEM EZ and Mannitol HS) on behalf of SPI Pharma of Grand Haven.

³⁰ Emphasis added.

³¹ Emphasis added.

Michigan USA) "32 Paragraph 11 of that agreement provides that SPI shall assist Drytec CP in registering its Tonbridge, England manufacturing site as required by the FDA and that as part of the registration Drytec CP shall name SPI as official agent. 33 Paragraph 12 of the agreement, addressing proprietary information, however, specifically acknowledges that SPI, not Drytec CP or any Co-Defendant, owns the technology of the spray dried mannitol/sorbitol products and any promotion by Drytec CP "of spray drying technology for use in mannitol/sorbitol processing . . . is expressly prohibited by" the agreement.

The cases dealing with agency, although addressing the concept in the parent-subsidiary relationship, are instructive.³⁴ When applying an agency theory, a court focuses on the arrangement between the entities, the authority given in that arrangement and the relevancy of that arrangement to the plaintiff's claim. The documents, discussed herein and relied upon by Roquette, confirm that SPI required that it be appointed as the agent so that SPI could import the mannitol product. The agreement shows that Drytec CP could not transact any business, perform any work or service, nor supply any services related to the alleged infringing product to anyone but SPI. The documents reveal that Drytec CP had no right to control the product at issue

³² Emphasis added. The title of the agreement is "SPI Pharma & Drytec Contract Processing Limited Commercial Letter of Agreement."

³³ Emphasis added.

³⁴ See generally, Monsanto Co. v. Syngenta Seeds, Inc., et. al., 443 F. Supp. 2d 636 (D. Del. 2006); Telcordia Technologies, Inc. v. Alcatel, C.A. No: C.A. No. 04-874 GMS, 2005 WL 128061 (D. Del. May 27, 2005); ACE & Company, Inc. v. Balfour Beatty PLC, 148 F. Supp. 2d 418 (D. Del. 2001); C.R. Bard, Inc. v. Guidant Corp., et. al., 997 F. Supp. 556 (D. Del. 1998); Applied Biosystems, In. v. Cruachem, Ltd., 772 F. Supp. 1458 (D. Del. 1991).

nor SPI in relation to that product. Moreover, under the agreement, Drytec CP was obligated to notify SPI if it was contacted by an SPI customer or regulatory agency regarding MANNOGEM™ EZ "or any SPI products made therefrom." There is no evidence that SPI sold or offered to sell the mannitol product for Co-Defendants or that SPI transacted any business, performed any work or service or supplied any services on Co-Defendants' behalf. There is no evidence of any parent-subsidiary relationship between SPI and any Co-Defendant. Therefore, whether SPI was Co-Defendants' "agent," there is no evidence to show that in an agency capacity SPI performed acts enumerated under § 3104(c) on behalf of Co-Defendants.

Anhydro Holding

Roquette has produced no evidence of any involvement by Anhydro Holding in the operations relating to mannitol production or the allegedly infringement products at issue. The sole "evidence" upon which Roquette relies is a press release on Anhydro Holding's website issued in January 2007, and the language contained therein which notes that "all member companies of the Anhydro Group . . . assumed the Anhydro name and became part of one single entity known as Anhydro." Roquette points to the "one single entity" phrase as evidence that approval was required by Anhydro Holding for Drytec CP's relationship with SPI. Although Roquette also relies on Kennet's deposition as proof that "review and approval of the tolling agreement" by Anhydro Holding was required, it ignores the full import of his testimony:

- Q. Would it be accurate to say that the Anhydro group is the successor to the Dedert group?
- A. No, that is not correct. Sorry, in terms of the ownership of the Drytec companies.

- Q. Yes.
- A. Yes, it would be.
- Q. Is it correct that major business decisions of the Drytec companies were subject to approval, information approval by the Dedert group or the Anhydro group of companies?
- A. It depends what you mean by "major decisions."
- Q. Can you enlighten me?
- A. Drytec CP in particular was an autonomous operating company, the only company either within the Dedert group or the Anhydro group subsequently that undertook toll processing. As such day-to-day decisions did not need to be referred to either Dedert or Anhydro. The only aspects which required holding company approval were major financial investments . . .
- A. Or commitments.³⁵

The above is the sum of Roquette's evidence regarding Anhydro Holding's alleged dealings with SPI or contacts with the state of Delaware. Personal jurisdiction over a foreign holding company in a patent infringement suit may not be exercised merely because of that corporation's relationship with an allegedly infringing subsidiary. Further, under Delaware law "to reach a parent corporation under the alter ego theory, the party asserting jurisdiction must establish some fraud, injustice, or inequity in the use of the corporate form." No such accusations have been raised or argued by Roquette. The mere fact that Anhydro Holding commented on its website that its regional sales companies were now part of the Anhydro family and, for some subsidiaries, would include the "Anhydro" name, is not evidence of the relationship

³⁵ Emphasis added.

³⁶ See Monsanto, 443 F. Supp. 2d at 645; *Telecordia*, 2005 WL 128061 at *2-3 *ACE & Co.*, 148 F. Supp. 2d at 422-23.

³⁷ C.R. Bard, Inc., 996 F. Supp at 559.

necessary for personal jurisdiction. In fact, this court has cautioned to avoid "the notion that a parent company can be held liable for the obligations of a subsidiary [under the agency theory] purely on the basis of dominion and control."³⁸ The agency theory requires evidence that "the precise conduct shown to be instigated by the parent be attributable to the parent."³⁹ Moreover, as Co-Defendants emphasize, even if an "approval requirement" exists as suggested by Roquette, there is no evidence that such occurred in Delaware or was required or occurred in this case.⁴⁰

There is no evidence that Anhydro Holding and the other Co-Defendants closely operate together. Roquette makes no attempt to address any of the *Applied Biosystems* factors which examines the amount of control that a parent exercises over the subsidiary to apply personal jurisdiction.⁴¹ Therefore, Anhydro Holding's position as the corporate parent is not sufficient to impose personal jurisdiction over it.

Specific Jurisdiction § $3104(c)(1),(2),(3)^{42}$

Personal jurisdiction under § 3104(c)(1), (2) or (3) is authorized if the defendant or its agent conducted any business or contracted to supply services or things in Delaware or caused a tortious injury within the state by conduct occurring in the forum. Section 3104(c)(1) requires that some act on the part of the defendant occur in Delaware and that the plaintiff's claims arise out of that act. Under § 3104(c)(2),

³⁸ *Id.* at 560, quoting *Mobile Oil Corp. v. Linear Films, Inc.*, 718 F. Supp 260, 271 n.15. (D. Del. 1989).

³⁹ *Id*.

⁴⁰ ACE & Co., 148 F. Supp. at 425.

⁴¹ 772 F. Supp at 1463.

⁴² The court need not address § 3104(c)(5) and (6) since there is no evidence that any Co-Defendant owns, uses or possesses any realty in Delaware or that they ever contracted to insure or act as a surety in this state.

shipping goods to Delaware is sufficient, however, the defendant must also perform the act in the state. Similarly, § 3104(c)(3) requires the tortious activity to occur in Delaware. To meet the requirements of § 3104(c)(1)-(3), the conduct of the defendant must be directed at the residents of Delaware and the protections of Delaware laws. However, the mere placement of a product into the stream of commerce with an awareness that it may end up in a specific state is not enough to establish minimum contacts. Further, when a manufacturer passes title to goods to a third party outside of Delaware, it has not performed an act in Delaware. Similarly, under Delaware law, the "[s]hipment of goods into a state by common carrier, without more, does not constitute transaction of business." When a foreign manufacturer designs, manufactures, labels and packages a product outside of Delaware, it has not performed those acts in the state and the specific jurisdiction provisions under § 3104(c)(1)-(3) do not apply.

Roquette does not dispute that the toll manufacturing agreement was an arrangement where SPI owned the raw materials used by Drytec CP in the manufacturing process, the interim product and the end accused product; that is, Drytec CP made the final product and the components and the finished product were owned by SPI throughout the entire process. There is no evidence that Co-Defendants ever

⁴³ *Moore v. Little Giant Industries, Inc.*, 513 F. Supp. 1043, 1046 (D. Del. 1981), *aff'd.*, 681 F.2d 807 (3d Cir. 1982).

⁴⁴ Thorn EMI N. Am. Inc. v. Micron Tech., Inc., 821 F. Supp. 272, 274 (D. Del. 1993).

⁴⁵ A.V. Imports, Inc. v. Col De Fratta, 171 F. Supp. 2d 369, 372 (D.N.J. 2001) (citing Asahi Metal Indus. Co. v. Superior Court, 480 U.S. 102, 107 (1987)).

⁴⁶ Boone v. Oy Partek Ab, 724 A.2d 1150, 1156 (Del. Super. 1997).

⁴⁷ *Moore*, 513 F. Supp. at 1046.

made, labeled or packaged the accused product within Delaware or the United States.

Roquette relies on documents which show that the alleged infringing product was shipped from Drytec CP or Drytec Ltd. to SPI in locations in Delaware. Roquette maintains that the invoices from those entities in 2001 and during July 2003, July 2004, January 2005 and April 2006, which reflect that the accused product was sent by Drytec CP, as the shipper, to SPI in Delaware meet the requirements of § 3104(c) and refute the supporting affidavits submitted by Co-Defendants. Apparently, Roquette contends that such documents prove that Co-Defendants imported infringing product (the tortious act) during that time on a continuous basis. By importing, Roquette argues that Co-Defendants fall within the provisions of § 3104(c)(1) through (3).

Despite Roquette's arguments to the contrary, reviewing the record as a whole, including the emails during the negotiations of the tolling agreement and the tolling agreement itself, reveal that all manufacturing of the alleged infringing product occurred outside Delaware and that Co-Defendants did not ship or have transported (imported) the accused product into Delaware. The transportation arrangements were under the control of SPI, who also owned the product through all stages of development and manufacture. The invoices and shipping records upon which Roquette relies during the 2001 through 2006 time period involve transfers of the accused product to SPI pursuant to the understanding among defendants, including SPI, that it was owner of the accused product and responsible for its importation. Although the tolling agreement expired after a year, the parties continued their relationship consistent with that

⁴⁸ Those locations are SPI facilities in Lewes and New Castle, Delaware and a warehouse in Newark, Delaware.

agreement for a period of time thereafter. The testimony of Paul Kennet confirms that Co-Defendants were not involved in the shipping or transportation arrangements from England to the United States during that time period. Further, the PIERS and the Department of the Treasury, United States Customs Service documents during that time period note SPI as the importer of record. The documents referenced by Roquette do not show who owned the accused product or who controlled its importation into the United States. The evidence shows that SPI directed where the accused product was to be sent once it left the facilities of Co-Defendants.

Moreover, subsection (c)(3) requires both an act be committed in Delaware and the injury to have occurred here. "The situs of the injury of patent infringement." however, is the place of the patent holder's residence."49 In the instant matter. Roquette is a corporation formed under the laws of France with its principal place of business in Cedex, France.

Roquette emphasizes the visit in 2000 by J.M. Pope ("Pope"), a managing director of certain Co-Defendants, which focused on a potential arrangement between Anhydro U.K./Drytec CP and SPI. Roquette surmises that the single Pope visit involved negotiations of the tolling agreement which resulted from negotiations that occurred in Delaware.50

⁴⁹ Applied Biosystems, Inc v. Cruachen, Ltd., 772 F. Supp. 1458, 1468 (D. Del.

<sup>1991).

50</sup> Subsequent to the briefing on the motion to dismiss, Roquette moved twice to after the deadline for limited augment its prior brief by adding information obtain after the deadline for limited discovery on the motion to dismiss, specifically portions of the deposition of Shuvashis Kayal ("Kayal"), SPI's President, Peter Dickinson ("Dickinson"), a former Quality Control Manager of Drytec CP and certain documents. Co-Defendants oppose Roquette's motions and the additional deposition information as being considered.

What the documents reveal is that in March 2000, representatives from SPI meet with Drytec CP in Britain. During that meeting the tolling arrangements were discussed as evidenced by a letter from Drytec CP to SPI dated March 21, 2000. Of note, the pricing for freight and packaging materials were not included and listed as extra. Also, new plant installation equipment apparently was discussed since information, such as, capacity requirements, heating apparatus and the air filtration standard was requested. Thereafter, in September 2000, Pope forwarded to SPI, a study memorandum which evaluated the efficacy of the Beacon Specialty Ingredients facility, a plant located in Michigan, under purchase by SPI, and "identif[ied] the synergies, advantages and disadvantages of Drytec and SPI utilising the Beacon facility."

An internal SPI memo dated September 17, 2000 confirms Pope's visit to Lewes, Delaware. The purpose of the visit was to discuss a possible pilot plant for a contract spray drying facility in Michigan (the Beacon facility). Various approaches to a potential arrangement for Drytec to locate its spray drying equipment business are outlined. The memo notes that further discussions were to occur later in England.

A subsequent letter from SPI dated October 2, 2000 discussed Pope's visit.

That letter solely addressed proposals related to the Beacon site as a possible pilot facility and contract manufacturing facility.

What those documents reveal is that discussions in Britain lead to a tolling arrangement between the parties, which eventually was memorialized in the tolling agreement in 2003. The visit to Lewes apparently focused on a possible pilot facility in Michigan, which never came to fruition.

Roquette relies on the Dickinson deposition as further support for specific

personal jurisdiction wherein Dickinson testified that he visited the SPI New Castle location one time to discuss sorbitol.

Roquette argues that the two visits show sufficient contacts with Delaware and Delaware as the location where the tolling agreement and/or agreement to supply drying equipment were negotiated. The testimony and additional documents, however, do not satisfy Roquette's burden to establish with reasonable particularity that its claims of infringement against Co-Defendants are related to the alleged visits to give rise to specific jurisdiction.

According to the documents, the purpose of Pope's visit to certain plants was to assist SPI in determining whether it had sufficient capabilities. None of the documents mention any negotiations or discussions regarding the tolling agreement. At most, they suggest approaches for use of the Beacon facility in Michigan, and a potential arrangement between Drytec CP/Anhydro U.K. and SPI regarding those uses. They also reveal that further discussion regarding those matters occurred in England.

Although Pope visited the Lewes plant, there is no evidence that any contract was negotiated in Delaware. Moreover, other documents proffered by Roquette show that discussions relating to the tolling agreement and the spray drying equipment occurred through email and letters. They also reveal that SPI representatives visited Co-Defendants' facilities in England. Such evidence is insufficient to conclude that any agreement or arrangement was negotiated in Delaware. Further, there is no evidence that Pope's single visit to Delaware related to the tolling agreement or production and

manufacture of the alleged infringing products.51

Roquette also proffers Dickinson's deposition to support specific jurisdiction. It argues that the Dickinson testimony coupled with the Pope evidence shows that two visits by high level managers of Co-defendants occurred and, along with the other documents, confers specific jurisdiction. Dickinson's testimony only reveals that he visited the SPI New Castle facility once to discuss sorbitol. Although one of the mannitol products at issue contains sorbitol, it is the mannitol that is alleged to infringe. Further the timing of this visit is unknown, but occurred many years prior to Dickinson's deposition. Since specific jurisdiction requires that some act on the part of Codefendants must have occurred in Delaware and that Roquette's claims arise out of that act, such a relationship has not been shown through the Dickinson testimony.

Here, ownership or title to the alleged infringing product remained with SPI and never passed to Co-defendants. Shipping arrangements as evidenced by the tolling agreement and other documents were made by SPI. The evidence shows that the manufacturing, labeling and packaging of the alleged infringing product occurred outside of Delaware. The two visits are not sufficient to establish transacting business in this jurisdiction and there is no showing that Roquette's claims arise out or are related to those meetings.

General Jurisdiction § 3104(c)(4)

Section 3104(c)(4) is a general jurisdiction provision in tort cases which allows the exercise of personal jurisdiction over a defendant where the defendant's

⁵¹ Boone, 724 A.2d at 1156.

connections with Delaware do not include activities that are the subject of the action, but where it, or through its agents, "regularly does or solicits business, engages in any other persistent course of conduct. . . or derives substantial revenue from services or things used or consumed in the State." Therefore, although this provision authorizes jurisdiction when both the tortious conduct and the injury occurred outside the state, the defendant must generally be present here. Whether a defendant derives substantial revenue from Delaware, two to three percent of the defendant's total revenue has been interpreted as sufficient to confer jurisdiction under that subpart.⁵²

Therefore, the focus is on whether Co-Defendants regularly do or solicit business, engage in any other persistent course of conduct *in the State* or derive substantial revenue from services, or things *used or consumed in the State*. As noted previously, for general jurisdiction to apply, a greater extent of contacts is required than under specific jurisdiction.

Clearly, the product in question was manufactured outside Delaware. No evidence has been presented that Co-Defendants have any offices or are physically present in Delaware. Further, the records show that all the spray-drying equipment sold by Anhydro U.K. to SPI was shipped to jurisdictions other than Delaware, specifically Pennsylvania, Michigan and Indiana. That equipment was ultimately sent to SPI's plant in Grand Haven, Michigan. There is no evidence that the equipment had any contact with Delaware. Moreover, the shipping documents related to that equipment show that

⁵² See United States v. Consolidated Rail Corp., 674 F. Supp. 138, 144 n.4 (D. Del. 1987). However, sales to customers in Delaware that constitute less than one percent of total revenue, do not qualify as substantial revenue. *Bell Helicopter Textron, Inc. v. C & C Helicopter Sales, Inc.*, 295 F. Supp. 2d 400, 405 (D. Del. 2002).

SPI was the importer of record, which suggests that the situs of the contract was England. As with the mannitol product, the equipment was not imported into the United States by Co-Defendants.

Absent the relationship with SPI, there is no evidence that Co-Defendants were involved in any business in Delaware. According to the documents, SPI was looking for a manufacturer of its product, MANNOGEM™ EZ. None of the documents suggest that Co-Defendants solicited SPI or any other customer in Delaware on a regular basis. Rather, it was SPI who procured and supplied the raw mannitol and searched for a manufacturer of its product over which it retained ownership from beginning to end.⁵³ As noted previously herein, only two visits by representatives of Drytec CP or Anhyro UK, one visit occurred in 2000 and the timing of the other visit is unknown. Those two meetings in Delaware are not contacts that are regular business efforts or solicitations or persistent conduct.⁵⁴

Regarding whether Co-Defendants derived substantial revenue from services or things used or consumed in Delaware, there is no evidence that the spraying drying equipment was ever utilized in this state. Rather, the documents note that such equipment was sent to another SPI facility in Michigan. Moreover, despite Roquette's argument that substantial income was derived from the sale of that equipment, it provides no analysis regarding the percentage of income from the sale of the

⁵³ From the documents, SPI selected the producer of mannitol, and originally used Getec, an affiliate of SPI.

⁵⁴ Helicopters Nacionels de Columbia S.A. v. Hall, 466 U.S. 408, 416 (1984); Mobile Oil Corp. v. Advanced Envtl. Recycling Technologies, 833 F. Supp 437, 445 (D. Del. 1993).

equipment in relation to Co-Defendants joint annual sales for 2005.⁵⁵ Of interest, none of the invoices or purchase orders for the equipment were in U.S. Dollars; rather, they were in British Pound Sterling suggesting that the business transacted for that equipment was in Britain and not the United States. No evidence has been presented regarding the income derived from the MANNOGEM™ EZ product in relation to total revenue.⁵⁶

Due Process

Although the court has concluded that Delaware law does not authorize the exercise of personal jurisdiction over the Co-Defendants, for the purpose of completeness, it will analyzed whether the assertion of personal jurisdiction comports with the requirements of due process. Since this matter involves federal patent law, the

⁵⁵ From the purchase orders attached, the equipment revenue for 2005 was £82,160, which converts to \$149,736.60, based upon the conversion rate of \$1.8225 as noted on the invoices. See D.I. 84, Ex. I. Applying Roquette's argument that Co-Defendants acted as "one single entity," their sales for 2005 totaled \$140,131,963, making the equipment sale to SPI equal to .11% of their annual sales. Even including the payments noted in the SPI email dated January 25, 2006 found at D.I. 84, Ex. I, those increase the total for the equipment sales in 2005 to \$224,336.67 or .16% of the annual sales for 2005.

substantial revenue from their long-term business dealings with SPI Pharma," solely because in a three week period in 2001, they billed \$50,000. See D.I. 84. Roquette, however, provides nothing on how it arrived at that supposition in relation to total revenues as required under *Bell Helicopter Textron*. Further, from the documents and other exhibits provided, the court was only able to calculate roughly \$92,000 in revenues in 2004 from the mannitol product. No information has been provide regarding the amount of revenue derived by Co-Defendants from that product or their total revenue in 2001 through 2005 or in 2006 when the last delivery of that product occurred. Although this opinion involves a motion to dismiss, it remains Roquette's responsibility to establish with reasonable particularity the required minimum contacts between the defendant and the forum state. *See Monsanto Co. v. Syngenta Seeds, Inc.*, 443 F. Supp. 2d 636, 642 (D. Del. 2006).

relevant constitutional provision is the Due Process Clause of the Fifth Amendment.⁵⁷

In the second prong of the analysis directed to due process concerns, in order to subject a defendant to personal jurisdiction, who is not present within the forum, the court must find, the existence of "minimum contacts" between the defendant and the forum state, "such that the maintenance of the suit does not offend 'traditional notions of fair play and substantial justice." Co-Defendants' conduct and connection with Delaware must be such that they should reasonably anticipate or foresee being "haled before a court" in the forum. Therefore, for the exercise of specific jurisdiction to be constitutional, Roquette must show that Co-Defendants "purposefully avail[ed] [themselves] of the privilege of conducting activities within the forum State, when the litigation arises out of those activities. Jurisdiction, for example, will not exist over a foreign entity when its alleged infringing product came into the forum state through the unilateral actions of a third party who had no pre-existing relationship with the tortfeasor.

Where the contacts do not relate to the cause of action, for general jurisdiction to be constitutional, "continuous and systematic contacts" with the forum state must be shown.⁶²

As the previous analysis herein suggests, Co-Defendants contacts with

⁵⁷ Max Daetwyler Corp. v. R. Meyer, 762 F.2d 290, 293 (3d Cir.

⁵⁸ International Shoe, 326 U.S. at 316.

⁵⁹ See World-Wide Volkswagen Corp. v. Woodson, 444 U.S. 286, 297 (1980); see also Asahi Metal Indus. Co. v. Superior Court, 480 U.S. 102, 108-109 (1987).

⁶⁰ Burger King v. Rudzewicz, 471 U.S. 462, 475 (1985) (quoting Hansen v. Denckla, 357 U.S. 235, 253 (1958)).

⁶¹ World-Wide Volkswagen Corp., 444 U.S. at 298.

⁶² Helicopteros Nacionales de Columbia, S.A., 466 U.S. at 414-415.

Delaware were minimal. There were two visits that, for the purpose of this discussion, arguably could have been related to the issues in suit. Such contacts do not rise to the level of "continuous and systematic" contacts with Delaware. The Pope visit did not deal with the alleged infringing mannitol product, but involved a possible future arrangement between SPI and certain Co-Defendants for a facility in Michigan, not Delaware. Another contact, when it occurred is unknown, involved sorbitol, a substance which is not at issue in this litigation. The documentary evidence does not suggest that the contract for the tolling agreement was negotiated in Delaware, or that the drying equipment was shipped to or used in Delaware.

Moreover, as noted previously herein, Co-Defendants never manufactured, produced, marketed or advertised the product at issue in the forum state. Although certain of the Co-Defendants "manufactured" the mannitol product, SPI always owned or controlled that product from the raw material stage through the final accused product, including its method, mode and location of importation into the United States. Under the tolling arrangement, Co-Defendants did not "sell" the alleged infringing product in Delaware; rather, they provided manufacturing capabilities to make that product, and those services occurred in Britain.

Roquette suggests that Co-Defendants admit to transacting business in Delaware, through the sale of the mannitol drying equipment, and, therefore, they have

⁶³ See Helicopteros Nacionales de Columbia, 466 U.S. at 416.

⁶⁴ Although Mannitol HS includes sorbitol, no evidence has been proffered regarding the timing, content or purpose of that meeting.

⁶⁵ See ICT Pharms., Inc. v. Boehringer Ingelheim Pharrms., Inc., 147 F. Supp. 2d 268, 272 (D. Del. 2001).

implicitly solicited business in the state, and also derived substantial revenue from Delaware. As previously analyzed herein, from the information provided, the revenue derived from that equipment was less than 1% of Co-Defendants' annual revenue for 2005, and therefore, not substantial enough to warrant an exercise of jurisdiction.

Further, as noted before, it is uncontested that Co-Defendants do not maintain any office, place of business, factory, mailing address or telephone listing in Delaware; they are not authorized, registered or qualified to do business in this state; and they have no agent for service of process here. Moreover, in *Asahi*, as here, where the plaintiff is not a resident of the forum state, the Supreme Court found that the interests of the forum in the litigation were "considerably diminished." 66

After considering the contacts that Co-Defendants have with Delaware, the court finds that the due process requirements are not satisfied because their business with this state is not continuous and systematic, nor does their conduct warrant a reasonable expectation of being haled before a court in this forum.

CONCLUSION

For the reasons contained herein, defendants Drytec Ltd., Drytec Contract Processing Ltd., Anhydro U.K. Ltd. and Anhydro Holding A/S motion to dismiss is granted. Since the court considered Roquette's two motions for leave to file a supplemental answering brief, its motions are granted. An Order consistent with this Memorandum Opinion shall follow.

⁶⁶ Asahi Metal Indus. Co., 480 U.S. at 114.